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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,494	03/07/2002	Joseph M. Patti	P06331US02/BAS	2645

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 08/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/091,494	PATTI ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-4,6,11-17 and 22-41* is/are rejected.

7)☐ Claim(s) *5,7-10 and 18-21,39,40* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-41 are pending.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejections Withdrawn

3. Claims 1,4-5,38-40,11,15-16,23,26-28,29,30-40 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, has been obviated through amendment of the claims to recite first and second staphylococcal adhesins, or Sdr proteins that have been described in the instant specification.
4. Claims 1,3-10,15-16,23,25-28,30,33-34,37,38-40 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is herein withdrawn in light of the various amendments of the claims and the definitions provided corresponding thereto providing clarity of the meets and bounds of the claims.
5. Claim 11 rejected under 35 U.S.C. 102(b) as being anticipated by Foster et al (US Pat. 6,008,341) in light of the amendment of claim to recite "human", to define the immunoglobulin produced by the method to be human immunoglobulin.
6. Claims 12-21,30-35 and 41 rejected under 35 U.S.C. 102(b) as being anticipated by Gristina et al is herein withdrawn in light of Applicant's traversal.
7. Claims 11, 12-17,11,29,30-36 and 41 rejected under 35 U.S.C. 102(b) as being anticipated by Stephan et al (US Pat. 4,965,068) in light of Applicant's traversal .
8. Claims 1-6,12-17,23-28,30-35,37,38-41 rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer in view of Wadstrom and Foster, in light of Applicant's traversal.

Rejections Maintained

9. Claims 22,29,and 36 rejected under 35 U.S.C. 102(b) as being anticipated by Foster et al (US Pat. 6,008,341) is maintained for reasons of record in paper number 3, and responses to arguments set forth below.
10. Claims 11,22,29, and 36 rejected under 35 U.S.C. 102(b) as being anticipated by Gristina et al is maintained for reasons of record in paper number 3, and responses set forth below.
11. Claims 1-4, 6 ("A domain" sequence shown at col. 61, lines 18-33, and comprises the consensus sequence YTFTDYVN, a sequence conserved between Sdr proteins) , 12-17,22,23-28,29,30-35,36,37,38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hook et al, for reasons of record in paper number 3 and responses set forth below.

Allowable Subject Matter

12. Claims 5,7-10,18-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

13. The rejection of claims 22,29,and 36 under 35 U.S.C. 102(b) as being anticipated by Foster et al (US Pat. 6,008,341) is traversed on the grounds that:

a. Foster does not remotely disclose the present method steps; nor

b. The specific high titer donor immunoglobulin compositions produced thereby;

c. The method of Foster is directed to the "simple preparation of a generic immune sera", and "immune sera obtained from immunizing rabbits, and not to a human immunoglobulin having a high titer to ClfA as in the claimed invention.";

d. no steps are disclosed to obtaining immunoglobulin compositions from human donors; and

e. concludes Foster et al does not disclose or suggest the claimed invention.

14. In response to Applicant's assertions, that Foster et al does not remotely disclose the present method steps, it is the position of the examiner that claims 22, 29 and 36 are directed to products not a method, and the claimed product may be produced by any process/method that produces the same or equivalent product.

15. In response to Applicant's assertions, that Foster et al does not disclose the specific high titer donor immunoglobulin compositions, Applicant is pointed to Table 2, column 11, where the

amount (concentration) of immunoglobulin (antisera) for N2 and N3, required for preventing adherence, was only 2.34 micro grams while the amount of the control immunoglobulin compositions,(preimmune and C2 (post immunization)), was over 300 micrograms showing a 150 times greater effectiveness of the N2 and N3 immunoglobulins for preventing bacterial adhesin; the antibodies being specific for ClfA, an Sdr protein.

Also see column 8, lines 30-33, where the antibodies are 2X the titer of the control, a high titer immunoglobulin composition. Also see Col. 2, lines 51-54, col. 10, lines 63-67; col. 6, line 15; col. 9, lines 36-37 which define the specific ClfA, Sdr proteins that were used in the process of obtaining immunoglobulins with a higher titer than non-selected donor immunoglobulin (control for the immunoglobulin compositions).

16. In response to Applicant's traversal directed to the method of Foster being a method for "simple preparation of a generic immune sera", and "immune sera obtained from immunizing rabbits, and not to a human immunoglobulin having a high titer to ClfA as in the claimed invention.", it is the position of the examiner that the instantly claimed immunoglobulin compositions do not require the immunoglobulins to be obtained from any specific mammal or source (instant claims 22,26 and 36), and are not limited to human immunoglobulins ; Applicant arguments are not commensurate in scope with the instantly claimed invention.

The immunoglobulin of claim 22 can be produced through administering ClfA to a host donor (claim 22 depends from independent claim 12), in order to obtain immune sera through recovering blood or plasma; Foster et al recovered anti-ClfA immunoglobulins in recovered blood (see col. 7-8), specifically blood sera.

17. In response to Applicant's assertions, that Foster et al does not disclose steps directed to obtaining immunoglobulin compositions from human donors, the examiner agrees. The claimed invention of claims 22, 29 and 36 are not required to be human immunoglobulin. Applicant's assertion is not commensurate in scope with the instantly claimed invention.

18. In response to Applicant's assertions, that Foster et al does not disclose or suggest the claimed invention, please see the responses above and the product by process case law immediately following this paragraph.

1. The claimed invention of claims 22, 29 and 36 are products produced by a process, but include products that may be produced by a different process, to obtain the same or equivalent process. Product by process case law teaches that citing of a reference against claims is appropriate when the reference or references teach a product that appears to be the same as, or an obvious variant of, the product set forth in a product-by-process claim although produced by a different process. See *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983) and *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP 2113. [T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product used in the claim and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

2. A similar approach is authorized in the case of product-by-process claims because the exact identity of the claimed product or the prior art product cannot be determined by the examiner. *In re Brown*, 450 F.2d 531, 173 USPQ 685 (CCPA 1972). In addition, although it is normally the best practice to rely on only the best prior art references in rejecting a claim, alternative grounds of rejection may be appropriate where the prior art shows elements that are different from each other, and different from the specific structure, material or acts described in the specification reasoning that the prior art factor appeared to differ from the claimed factor only in the method of obtaining the factor. The Board held that the burden of persuasion was on appellant to show that the claimed product exhibited unexpected properties compared with that of the prior art. The Board further noted that "no objective evidence has been provided establishing that no method was known to those skilled in this field whereby the claimed material might have been synthesized." 10 USPQ2d at 1926.).

19. Foster et al disclose the same or equivalent products produced by a different process. Foster et al disclose the instantly claimed products of claims 22, 29 and 36, produced by a different method. While claim 11 has been amended to be directed to human immunoglobulin, claims 22, 29 and 36 may be immunoglobulin obtained from any source, and need not be human immunoglobulin. The prior art rejection is maintained for reasons of record.

20. The rejection of claims 11,22,29, and 36 under 35 U.S.C. 102(b) as being anticipated by Gristina et al traversed on the grounds that: Grista does not carry out the screening methods steps of the instantly claimed methods.

21. Gristina et al was applied against the instantly claimed product claims, the claims being defined by a process, but not limited thereto as long as the same or an equivalent composition of human immunoglobulin or human donor immunoglobulin is obtained by another process. See product by process case law set forth above.

With respect to the cited references, Wickelhaus et al (1999) and Nicholas et al (1999) and the existence of strains of S.aureus that do not comprise clumping factor, while this is true, the Wickelhaus et al reference provides evidence that 149/150 strains are clumping factor positive, which is 99.3% of the strains were clumping factor positive; and the clumping factor negative strains are area specific to Frankfort.

Upon reconsideration of Applicant's assertions that the compositions of Gristina et al does not comprise human immunoglobulins specific for S.epidermidis and S.aureus surface associated antigens, specifically adhesins (clumping factor and Sdr proteins), it was noted that Applicant's assertions have not been substantiated by submission of extrinsic evidence that

shows that asserted novelty of the instantly claimed product, produced by the recited process steps, wherein the claimed product produced by a different but equivalent process, anticipates the instantly claimed invention. Grista et al teach pooled human donor immunoglobulin that inherently comprise antibodies directed to surface associated proteins, which are virulence factors that adhere to the host animals receptors. WO94/13310, WO94/18327 and WO95/34655 were provided as evidence that S.aureus and S.epidermidis stains both produce Sdr and clumping factor adhesins during the normal course of infection and stimulate an immune response thereto.

The rejection is maintained for reasons of record in paper number 3.

22. The rejection of claims 1-4, 6 ("A domain" sequence shown at col. 61, lines 18-33, and comprises the consensus sequence YTFTDYVN, a sequence conserved between Sdr proteins) , 12-17,22,23-28,29,30-35,36,37,38-41 rejected under 35 U.S.C. 103(a) as being unpatentable over Hook et al, is traversed on the grounds that:

the Hook et al reference does not suggest human donor immunoglobulin to ClfA.

23. It is the position of the examiner that the Hook et al reference does suggest human donor immunoglobulin to ClfA. Applicant is directed to column 12, lines 46-52, where humans are immunized with the peptide antigens disclosed therein for the purpose of generating an immune response (see col. 12, line 37) . ClfA peptide antigen is described at Col. 67, lines 18-33, for the generation of and provision for "passive immunization (see col. 59, lines 25-36). Immunoglobulin obtained from human donor volunteers is taught (see col. 12, lines 24-45). Immunoglobulin to a second Staphylococcal adhesin is taught for in vivo inhibition of bacterial colonization (see col. 18, lines 36 and 37-41 and lines 63-67 "inhibiting bacterial colonization"

and col. 19, lines 1-11). At column 30, section 4.10. human donors are taught to be immunized for preparing immunoglobulin (antibody) compositions. A second location in the reference that teaches the immunization of human donors is col. 12, lines 45-52 "particularly humans").

24. Applicant assets that donor immunoglobulin of Hook et al is not high titer as set forth in the claims of the present application.

25. Hook et al, teach immunization of donor mammals (see col. 61, lines 43-45; and col. 48-63) and suggest the immunization of humans (see col. 12, line 52), as well as teach a method of obtaining immunoglobulin directed against staphylococcal adhesins (see "Anti-MSCRAMM IgG for passive immunization, section 5.3.8 and 4.25, 5. Examples) from blood, recovering blood with a high titer and treating the donor blood to obtain immunoglobulin in a purified state is taught, especially :

26. **immunizing and obtaining blood** (see col. 50, line 23 "col, Fn and Fbg-binding MSCRAMMs"; col. 30, lines 51-52); col. 51, lines 26-27 ("Immunized" and "collected");

27. **recovering high titer** (ELISA with synthetic peptides to determine the antiserum reactivity (titer, col. 51, lines 29-31);

28. **treating** the blood to obtain purified immunoglobulin (see "purified IgG reacted strongly", "preimmune IgG "... "little reaction could be detected" (col. 51, lines 34-35 and lines 39-48).

29. Applicant asserts that the only reference to the production of antibodies in humans is with regard to CBP.

30. While it is true that the reference teaches the production of antibodies in humans for CBP, the reference also teaches the generation of antibodies to the peptides disclosed therein (col. 12) which include ClfA peptide (col. 61), as well as other adhesin peptides referred to as MSCRAMM peptides" and teach the exemplified methods used for CBP are applicable to other adhesins described therein and, the references teaches the utilization of a "combination" of adhesins for the generation of antibodies directed against streptococcal and staphylococcal adhesins, wherein the antibodies provide for generating a synergistic effect in the treatment of infection (se col. 26, lines 7-17, especially line 12).

31. The Hook et al reference is additionally traversed as not describing any high titer donor composition with a high titer to any adhesin, "much less the particular human immunoglobulin composition".

32. Hook et al did immunize, recover and determine a high titer immunoglobulin composition from rabbits, and suggested the immunization of human to recover anti-adhesin protective immunoglobulin antibodies.

The prior art rejection is maintained for reasons of record.

New Grounds of Objection and Rejection

Claim Rejections - 35 USC § 112

33. Regarding claim 38, the phrase "and other proteins" is analogous to the phrase "or the like", and therefore renders the claim indefinite because the claim includes elements not actually disclosed (those encompassed by "and other proteins that bind to extra cellular matrix proteins

(instant claim 38), a phrase analogous to "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Double Patenting

34. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

35. Claims 11,22,29 and 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims1-11, and 14-24 of U.S. Patent No. 6692739. Although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed species anticipates the instantly claimed genus of immunoglobulins, the immunoglobulins being directed to a combination staphylococcal adhesins (see instant claims 1 and 5, which include both S.aureus and S.epidermidis adhesins) .

36. Claims 22, 29 and 36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,3,12,13 of copending Application No. PG-Pub 2004/0038327 in view of Swiss-Prot sequence search showing the conserved sequence TYTFTDYVD or YTFTDYVD present in both in Sdr and ClfA proteins of S.aureus and S.epidermidis; the pending species anticipates the instantly claimed genus of

immunoglobulin/antibodies with the binding specificity of the recited amino acid sequence cited above, as immunoglobulins directed to ClfA and Sdr protein adhesins of staphylococcus would comprise antibodies to this sequence that is immunogenic and immunoreactive as it is a highly conserved, immunogenic region of staphylococcal adhesin proteins. This is a provisional obviousness-type double patenting rejection.

37. Claims 11, 22, 29 and 36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,6, 33-36 (human monoclonal antibodies; instant claim 11) and 1-15, 37 (instant claims 22,29,36) of copending Application No. PG-Pub 2003/0099656 ; the pending species anticipates the instantly claimed genus of immunoglobulin/antibodies with the binding specificity directed to ClfA or Sdr protein adhesin of staphylococcus because a monoclonal antibody is a species of the instantly claimed genus of immunoglobulin with the recited binding specificity of ClfA or Sdr protein of staphylococcus. This is a provisional obviousness-type double patenting rejection.

38. Claims 29 and 36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11, 16-17, 19-21,23 (instant claims 29,36) of copending Application No. PG-Pub 2003/0006209; the co-pending species anticipates the instantly claimed genus of immunoglobulin/antibodies with the binding specificity directed to a Sdr protein adhesin of staphylococcus because a antibody directed to a specific Sdr protein, specifically SdrG, and a monoclonal antibody directed thereto is a species of the instantly claimed genus of immunoglobulin with the recited binding specificity directed to

any Sdr protein of staphylococcus. This is a provisional obviousness-type double patenting rejection.

Claim Objections

39. Claims 39 and 40 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

40. Claims 39 and 40 recite the term "MHCII"; while the claim recites staphylococcal adhesion, this abbreviation recited is known in the art to be representative of a genus of molecules known as major histocompatability complex, class II antigens, and is not limited to just Staphylococcal antigens, as the antigen is also present, for example, in humans, as well as other known prokaryotic cells. Therefore the broad recitation of MHCII does not define the antigen being limited to a Staphylococcal antigen which is known as MHCII analogous protein as recited in instant claim 38.

Conclusion

41. This is a non-final action.

42. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

43. Boden Wasfalt et al (US Pat. 6,299,879) is cited to show a method of providing passive immunity to a mammal (see claim 2), the immunoglobulin comprising antibodies directed against Staphylococcus fibrinogen binding protein.

44. PG-Pub US 2004/0142348 A1 (Foster et al) is cited to show S.epidermidis Sdr proteins, SdrF, SdrG, and SdrH which comprise the conserved amino acid consensus sequence TYYFTDYVD.

45. (Foster et al) US Pat. 6,177,084 is cited to show antibodies to Staphylococcus clumping factor (also known as S.aureus fibrinogen binding protein).

46. (Guss et al, effective filing date Dec. 24, 1997)US Pat. 6,733,758 B1 is cited to show S.aureus and S.epidermidis fibrinogen binding protein and inhibitory antibodies that functioned to prevent S.epidermidis binding to immobilized fibrinogen (see col. 6, lines 33-43).

47. (Hook et al) US Pat. 5,648,240 is cited to show MHC II analog from Staphylococcus aureus.

48. (Hook et al) US Pat. 6,685,943 B1 is cited to show truncated peptides that induce antibodies specific to S.aureus fibronectin binding proteins.

49. Kuusela et al (US Pat. 5,496,706) is cited to show antibodies immunoreactive (see Example 2, col. 4, lines 50-64; and claim 4 "antibodies in kit composition) with methicillin resistant strains of S.aureus.

50. Kuusela et al (US Pat. 5,776,712) is cited to show antibodies immunoreactive with methicillin resistant strains of S.aureus (see all claims and entire reference).

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on 7:30-5:00 M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
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